

CLAIMS

1. An active-containing dissolvable film prepared by forming a mixture comprising an active ingredient and film-forming ingredients, coating the mixture onto a substrate material to form a film, and then drying the film to a moisture content of less than about 15 weight % moisture, said active ingredient having a water solubility of less than about 4 g/mL at room temperature and being present in the film in amounts sufficient to impart a desired action upon administration of a single dosage form of the active-containing dissolvable film.
2. The film of claim 1 wherein the active ingredient has a water solubility of less than about 10 g/mL at room temperature.
3. The film of claim 1 wherein the mixture is in the form of a solution.
4. The film of claim 3 wherein a solution is formed upon the application of heat and/or agitation of the mixture.
5. The film of claim 1 wherein the mixture is in the form a suspension.

6. The film of claim 3 wherein said active ingredient is caffeine.
7. The film of claim 6 comprising at least about 18 % by dry weight of caffeine based on the weight of the final formulated film.
8. The film of claim 7 comprising at least about 20 % by dry weight of caffeine.
9. The film of claim 8 comprising at least about 25 % by dry weight of caffeine.
10. The film of claim 1 wherein said film-forming ingredients comprise a starch component comprising at least about 85 % modified starch.
11. The film of claim 10 wherein the starch is selected from the group consisting of a hydroxyalkylated starch and a succinated starch.
12. A method of making an active-containing dissolvable film comprising an active ingredient, the method comprising forming a mixture of an active ingredient and film-forming ingredients,

coating the mixture onto a substrate material to form a film, and then drying the film to a moisture content of less than about 15 weight % moisture, said active ingredient having a water solubility of less than about 1g/4mL at room temperature and used in amounts sufficient to impart a desired action upon administration of a single dosage form of the active-containing dissolvable film.

13. The method of claim 12 wherein the mixture is in the form of a solution or in the form of a suspension.

14. A dissolvable caffeine-containing film comprising at least about 18 % by dry weight of caffeine based on the weight of said film.

15. A single dosage dissolvable film of claim 14 comprising from about 20 mg to about 30 mg of caffeine per single dosage film.

16. A method of administering an active ingredient to an individual needing or desiring said active ingredient, said method comprising applying the active-containing dissolvable film of claim 1 to a moist area of an individual, upon which application the active is released.

17. The method of claim 16, wherein the film is applied to the tongue.

18. The method of claim 16, wherein the film is applied to traumatized tissue.

19. The method of claim 18 wherein the traumatized tissue is skin.

20. The method of claim 17 wherein the active ingredient is caffeine.